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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,725	01/15/2004	E. Scott Priestley	PH-7148A DIV1	8195

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,725	PRIESTLEY, E. SCOTT	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The present case is a Divisional of allowed application 10/039,317. Applicant's preliminary amendment of 01/15/2004 is acknowledged. Although each are separated as distinct inventions below due to distinct compound structures (including the methods of using each respectively), it is noted at the outset that dependent claim 17 (29 compounds all containing the 5 residue peptide H-Asp-Glu-Val-Val-Pro) and dependent claim 18 (6 compounds all containing the 2 residue peptide Ac-Val-Pro) improperly depend from independent claim 16 (broad formula wherein R3 must be the 3 residue peptide H-Asp-Glu-Val or non-peptide acetyl), since all the claimed limitations are not present in the dependent claims. Specifically, R3 of the formula of independent claim 16 must be either the 3-residue peptide H-Asp-Glu-Val or acetyl, which none of the compounds of dependent claims 17 and 18 contain. If claim 17 or claim 18 is elected as the invention or a claim 20 (method of using the compounds of one of claim 16, 17, or 18), it is recommended that Applicant amend that claim to include the formula commensurate in scope to the claimed compounds of that Group. Claims 1-15 have been cancelled, and claims 16-20 remain pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 16 and 19 are drawn to a compound or pharmaceutical composition wherein R3 must be the 3-residue peptide H-Asp-Glu-Val or non-peptide acetyl, classified in class 530, subclass 300+.

II. Claims 17 and 19 are drawn to 29 specific compounds or pharmaceutical compositions all containing the 5-residue peptide H-Asp-Glu-Val-Val-Pro, classified in class 530, subclass 300+.

III. Claims 18 and 19 are drawn to 6 specific compounds or pharmaceutical compositions all containing the 2-residue peptide Ac-Val-Pro, classified in class 530, subclass 300+.

IV. Claim 20 are drawn to a method of treating HCV infection using a compound wherein R3 must be the 3-residue peptide H-Asp-Glu-Val or non-peptide acetyl, classified in class 514, subclass 2.

V. Claims 20 are drawn to a method of treating HCV infection using the 29 specific compounds or all containing the 5-residue peptide H-Asp-Glu-Val-Val-Pro, classified in class 514, subclass 2.

VI. Claims 20 are drawn to a method of treating HCV infection using the 6 specific compounds all containing the 2 residue peptide Ac-Val-Pro, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the

different inventions (compounds/compositions) all include separate and distinct peptide structures (i.e. 2mer, 3mer, 5mer peptides) or alternatively no peptide at all (R3 alternative Group I); where it is well known in the peptide arts that different amino acid residue (non-conservative) exhibit different properties and small peptides containing such different functions.

Inventions IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions (methods) all use separate and distinct peptide structures (i.e. 2mer, 3mer, 5mer peptides) or alternatively no peptide at all (R3 alternative Group I); where it is well known in the peptide arts that different amino acid residue (non-conservative) exhibit different properties and small peptides containing such different functions.

Inventions I-III and IV-VI are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods may be practiced by any of the myriad of different peptide or non-peptide compounds capable of use in the invention.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group.

Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention (depending on which invention is elected):

Group I or IV – the 2 distinct species compounds containing either the 3 residue peptide H-Asp-Glu-Val or non-peptide acetyl;

Group II or V – the 29 distinct species compounds all containing the 5-residue peptide H-Asp-Glu-Val-Val-Pro;

Group III or VI – the 6 distinct species compounds all containing the 2-residue peptide Ac-Val-Pro.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, from the elected Group above, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 16, 17, and 18 (and corresponding claim 20) are generic to their respective compound structures.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA
10/18/04

CHRISTOPHER R. TATE
PRIMARY EXAMINER